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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,775	03/31/2000	JUN FUJITA	053466/0277	9739

22428 7590 02/11/2003

FOLEY AND LARDNER
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER
YU, MISOOK

ART UNIT	PAPER NUMBER
1642	23

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/509,775	FUJITA, JUN	
	Examiner	Art Unit	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,16,17 and 35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 5, 16, 17, and 35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☒ Interview Summary (PTO-413) Paper No(s). *22* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: Seq. Alignment

The Examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Misook Yu.

DETAILED ACTION

The finality of the previous Office action has been withdrawn. Applicant's submission filed on 10-04-2002 has been entered.

Claims 1, 5, 16, 17, and 35 are pending and examined on merits.

Claim Rejections - 35 USC § 112

Rejection of claim 5 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention **is withdrawn** because the specification at page 12 lines 1-2 has support for the hybridization condition recited in the instant claim as applicant pointed out in Paper No. 19.

New Grounds of Rejection

Claim Objections

Claim 16 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The protein in the base claim is limited to protein without a signal sequence but the dependent claim 16 is drawn to protein with a signal sequence.

Claim Rejections - 35 USC § 112

Claims 1, 16, and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation " the biological property of gankyrin " in 2-3. There is insufficient antecedent basis for this limitation in the claim.

Claim 1 recites "a signal sequence" but it is not clear what the metes and bounds are for the limitation. Does the signal sequence reside within the claimed gankyrin

polypeptide for example in residue 1 to 13 of SEQ ID NO:2 or it is a foreign sequence? The specification does not teach any signal sequence in gankyrin. Why a signal sequence excluded in claim 1 but include in claim 16?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

On reconsideration, **rejection** of claim 1 under 35 U.S.C. 102(b) as being anticipated by Kato et al (IDS, JP 9-75085, published 25 March 1997) **is reinstated** and claims 5, and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Kato (IDS, JP 9-75085, published 25 March 1997).

Claim 1 is interpreted as drawn to a polypeptide **comprising** amino acid #14 to #226 of SEQ ID NO:2. Applicant's argument in Paper No. 13 that Kato does not teach the polypeptide of claim 1 possessing gankyrin biological activity is not convincing because biological activity is an inherent property of the protein. Since Kato teaches the human 26S proteosome subunit (P28) with the identical structure as the instant SEQ ID NO:2 (note the attached sequence alignment), it necessarily possesses the same inherent biological properties. The protein taught by Kato comprises #14 to #226 of SEQ ID NO:2. Further the specification does not teach any biological differences between the instantly claimed protein and the protein taught by Kato et al. The biological property of gankyrin is same as the biological property of 26S proteosome subunit (P28). Further, neither the specification nor Kato teaches gankyrin (26S proteosome subunit (P28)) has any signal sequence so the protein taught by Kato does not appear to contain a signal sequence.

Claim 5 and 35 are interpreted as drawn to SEQ ID NO:2 and Kato teaches SEQ ID NO:2 as discussed above. The biological properties recited in the instant claims are inherent properties of the human 26S proteosome subunit (P28) taught by Kato since the instant SEQ ID NO:2 and the protein taught by Kato are identical.

Thus, Kato et al anticipate claims 1, 5, and 35.

Claim Rejections - 35 USC § 103

On reconsideration, **rejection of claims 16 and 17** under 35 U.S.C. 103(a) as being unpatentable over Kato (IDS, JP 9-75085, published 25 March 1997) as applied to claim 1 above, and further in view of Zhang et al (1995, a copy provided in the previous Office action) and Jamsa et al (1995, a copy provided in the previous Office action) **is reinstated**.

Applicant argument in Paper No. 13 at page 4 that Kato does not teach a polypeptide starting with alanine at position 14 of SEQ ID NO:2 exhibiting gankyrin biological activity and there is no objective motivation to combine the cited references within the knowledge of one of ordinary skill, specifically one of ordinary skill would not read Kato, Zhang, and/or Jama, or any combination thereof and produce a fusion protein containing a shortened version (i.e., lacking first 13 amino acids at the N-terminal end) of the full length gankyrin polypeptide which retains its biological activity, is not convincing because instant claim 1 reads on the human 26S proteosome subunit (P28) taught by Kato (see art rejection of claim 1 above) since instant claim 1 is drawn to a protein **comprising** amino acid #14 to #226 of SEQ ID NO:2. Applicant does not argue that Jamsa et al (1995) teach a useful signal sequence, and Zhang et al (1995) teach why one would be motivated to make a fusion protein by attaching a foreign peptide or a signal sequence to instant SEQ ID NO:2.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-

305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu
February 4, 2003

SHEELA HUFF
PRIMARY EXAMINER

GenCore version 4.5

OM protein - protein search, using sw model

Run on: August 13, 2001, 07:44:23 ; Search time 32.29 Seconds
(without alignments)
424.312 Million cell updates/sec

Title: US-09-509-775-2
Perfect score: 1164
Sequence: 1 MEGCVSNLMVCNLAYSGKLE.....TPLQVAKGGLGLILKRMVEG 226

Scoring table: BLOSUM62
Gapop 10.0 , Gapext 0.5

Searched: 412676 seqs, 60623988 residues

Total number of hits satisfying chosen parameters: 412676

Minimum DB seq length: 0
Maximum DB seq length: 2000000000

Post-processing: Minimum Match 0%
Maximum Match 100%
Listing first 45 summaries

Database : A_Geneseq_0601:*
1: /SIDS1/gcgdata/geneseq/geneseqp/AA1980.DAT:*
2: /SIDS1/gcgdata/geneseq/geneseqp/AA1981.DAT:*
3: /SIDS1/gcgdata/geneseq/geneseqp/AA1982.DAT:*
4: /SIDS1/gcgdata/geneseq/geneseqp/AA1983.DAT:*
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6: /SIDS1/gcgdata/geneseq/geneseqp/AA1985.DAT:*
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21: /SIDS1/gcgdata/geneseq/geneseqp/AA2000.DAT:*
22: /SIDS1/gcgdata/geneseq/geneseqp/AA2001.DAT:*

Pred. No. is the number of results predicted by chance to have a score greater than or equal to the score of the result being printed, and is derived by analysis of the total score distribution.

SUMMARIES

Result No.	Score	% Query Match	Length	DB	ID	Description
1	1164	100.0	226	18	AAW15483	Human P28. Homo s
2	1164	100.0	226	20	AAY02430	Human gankyrin pro
3	1110	95.4	231	20	AAY02432	Rat gankyrin prote
4	1105	94.9	231	20	AAY02431	Mouse gankyrin pro
5	288.5	24.8	1166	22	AAB47022	Human SPANK. Homo
6	287	24.7	352	21	AAB11616	D. immitis ankyrin
7	287	24.7	1745	19	AAW70608	Full length ankyri
8	287	24.7	1745	19	AAW76776	D. immitis ankyrin
9	287	24.7	1745	21	AAB11589	D. immitis ankyrin
10	283.5	24.4	522	22	AAB66287	Human tankyrase2 c
11	283.5	24.4	1166	22	AAB66295	Human tankyrase2 T
12	283.5	24.4	1169	22	AAB66278	Human tankyrase2 r
13	283.5	24.4	1169	22	AAB66288	Human tankyrase2 c
14	283.5	24.4	1262	22	AAB66290	Human tankyrase2 c
15	283.5	24.4	1385	22	AAB66294	Human tankyrase2 T
16	281.5	24.2	673	21	AAY44403	Human truncated ta
17	281.5	24.2	949	21	AAY44404	Human truncated ta
18	281.5	24.2	991	22	AAB47023	Mouse SPANK. Mus
19	281.5	24.2	1327	21	AAB27212	Human tankyrase I
20	281.5	24.2	1327	21	AAY44402	Human tankyrase.
21	281.5	24.2	1327	22	AAB66279	Human tankyrasel S
22	281	24.1	1181	22	AAB66297	Drosophila tankyra
23	280.5	24.1	1166	22	AAY72589	Human tankyrase ho
24	277.5	23.8	1166	21	AAB27211	Human tankyrase II
25	271	23.3	302	19	AAW70609	Ankyrin protein PB
26	271	23.3	302	19	AAW76777	B. malayi ankyrin
27	271	23.3	302	21	AAB11590	B. malaya ankyrin
28	270.5	23.2	1030	19	AAW53572	Human myosin light
29	270.5	23.2	1030	19	AAW41378	Human protein p164
30	269.5	23.2	976	19	AAW53571	Rat p138 protein.
31	269.5	23.2	976	19	AAW41377	Rat protein p138.
32	269	23.1	1074	20	AAY05734	Human Grb7 effecto
33	265	22.8	756	22	AAB66286	Human tankyrase2 c
34	265	22.8	784	22	AAB66285	Human tankyrase2 c
35	265	22.8	907	22	AAB48574	Human breast cance
36	262	22.5	303	19	AAW70606	Ankyrin protein fr
37	262	22.5	303	19	AAW76774	D. immitis ankyrin
38	262	22.5	303	21	AAB11587	D. immitis ankyrin
39	260.5	22.4	978	21	AAB42288	Human ORFX ORF2052
40	258.5	22.2	763	21	AAY79154	Mouse protein kina
41	258.5	22.2	786	21	AAY69163	Amino acid sequenc
42	258.5	22.2	787	21	AAY76079	Murine protein kin
43	258.5	22.2	787	22	AAB56018	Skin cell protein,
44	252.5	21.7	456	21	AAG12893	Arabidopsis thalia
45	252.5	21.7	456	21	AAG27402	Arabidopsis thalia

ALIGNMENTS

RESULT 1
AAW15483
ID AAW15483 standard; Protein; 226 AA.
XX
AC AAW15483;
XX
DT 17-JUN-1997 (first entry)
XX
DE Human P28.
XX
KW Human; proteasome; P28; diagnosis; malignant tumour.
XX
OS Homo sapiens.
XX
PN JP09075085-A.
XX
PD 25-MAR-1997.
XX
PF 13-SEP-1995; 95JP-0235052.
XX
PR 13-SEP-1995; 95JP-0235052.
XX
PA (SAGA) SAGAMI CHEM RES CENTRE.
XX
DR WPI; 1997-239267/22.
DR N-PSDB; AAT66424-25.
XX
PT Human 26S proteasome constituting component protein - useful in the
PT diagnosis of e.g. malignant tumour
XX
PS Claim 1; Page 6-7; 9pp; Japanese.
XX
CC This sequence represents the human proteasome component protein P28.
CC The protein, P28, is useful for the diagnosis and treatment of

```
CC   various diseases caused by proteasomes such as malignant tumour.
XX
SQ   Sequence   226 AA;


  Query Match           100.0%;  Score 1164;  DB 18;  Length 226;
  Best Local Similarity  100.0%;  Pred. No. 5e-119;
  Matches  226;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy      1 MEGCVSNLMVCNLAYSGKLEELKESILADKSLATRTDQDSRTALHWACSAGHTEIVEFLL 60
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      1 megcvsnlmvcnlaysgkleelkesiladkslatrtdqdsrtalhwacsaghteivefll 60

Qy     61 QLGVPVNDKDDAGWSPLHIAASAGRDEIVKALLGKGAQVNAVNQNGCTPLHYAASKNRHE 120
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     61 qlgvpvndkddagwsplhiaasagrdeivkallgkgaqvnavnqngctplhyaasknrhe 120

Qy    121 IAVMLLEGGANPDAKDHYEATAMHRAAAKGNLKMIHILLYYKASTNIQDTEGNTPLHLAC 180
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db    121 iavmllegganpdakdhyeatamhraaakgnlkmihillyykastniqdtegntplhlac 180

Qy    181 DEERVEEAKLLVSQGASIYIENKEEKTPLQVAKGGLGLILKRMVEG 226
          ||||||||||||||||||||||||||||||||||||||||||||||
Db    181 deerveeakllvsqgasiyienkeektplqvakgglglilkrmveg 226


RESULT   2
AAY02430
ID   AAY02430 standard; Protein; 226 AA.
XX
AC   AAY02430;
XX
DT   14-JUL-1999  (first entry)
XX
DE   Human gankyrin protein.
XX
KW   Gankyrin; apoptosis induction; diagnosis; treatment; cancer;
KW   hepatocellular carcinoma; oncogenesis mechanism.
XX
OS   Homo sapiens.
XX
PN   WO9918201-A1.
XX
PD   15-APR-1999.
XX
PF   02-OCT-1998;   98WO-JP04467.
XX
PR   03-OCT-1997;   97JP-0286214.
XX
PA   (FUJI/) FUJITA.
XX
PI   Fujita J;
XX
DR   WPI; 1999-277266/23.
DR   N-PSDB; AAX35852.
XX
PT   Gankyrin polypeptides, useful for treatment and diagnosis of
PT   cancers, e.g. hepatocellular carcinoma, and study of oncogenesis
PT   mechanism
XX
PS   Claim 1; Page 70-71; 111pp; Japanese.
XX
CC   The specification describes human, murine and rat gankyrin DNA and
CC   polypeptide sequences. Gankyrin polypeptides inhibit tumorigenic
CC   ability and apoptosis induction. The polypeptides and their antibodies
CC   can be used in the diagnosis and treatment of cancers,
CC   e.g. hepatocellular carcinoma, and study of oncogenesis mechanism.
CC   The present sequence represents human gankyrin.
XX
SQ   Sequence   226 AA;


  Query Match           100.0%;  Score 1164;  DB 20;  Length 226;
  Best Local Similarity  100.0%;  Pred. No. 5e-119;
  Matches  226;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy      1 MEGCVSNLMVCNLAYSGKLEELKESILADKSLATRTDQDSRTALHWACSAGHTEIVEFLL 60
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      1 megcvsnlmvcnlaysgkleelkesiladkslatrtdqdsrtalhwacsaghteivefll 60

Qy     61 QLGVPVNDKDDAGWSPLHIAASAGRDEIVKALLGKGAQVNAVNQNGCTPLHYAASKNRHE 120
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     61 qlgvpvndkddagwsplhiaasagrdeivkallgkgaqvnavnqngctplhyaasknrhe 120

Qy    121 IAVMLLEGGANPDAKDHYEATAMHRAAAKGNLKMIHILLYYKASTNIQDTEGNTPLHLAC 180
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db    121 iavmllegganpdakdhyeatamhraaakgnlkmihillyykastniqdtegntplhlac 180

Qy    181 DEERVEEAKLLVSQGASIYIENKEEKTPLQVAKGGLGLILKRMVEG 226
          ||||||||||||||||||||||||||||||||||||||||||||||
Db    181 deerveeakllvsqgasiyienkeektplqvakgglglilkrmveg 226


RESULT   3
AAY02432
ID   AAY02432 standard; Protein; 231 AA.
XX
AC   AAY02432;
XX
DT   14-JUL-1999  (first entry)
XX
DE   Rat gankyrin protein.
XX
KW   Gankyrin; apoptosis induction; diagnosis; treatment; cancer;
KW   hepatocellular carcinoma; oncogenesis mechanism.
XX
OS   Rattus sp.
XX
PN   WO9918201-A1.
XX
PD   15-APR-1999.
XX
PF   02-OCT-1998;   98WO-JP04467.
XX
PR   03-OCT-1997;   97JP-0286214.
XX
PA   (FUJI/) FUJITA.
XX
PI   Fujita J;
XX
DR   WPI; 1999-277266/23.
DR   N-PSDB; AAX35854.
XX
PT   Gankyrin polypeptides, useful for treatment and diagnosis of
PT   cancers, e.g. hepatocellular carcinoma, and study of oncogenesis
PT   mechanism
XX
PS   Claim 11; Page 76-78; 111pp; Japanese.
XX
CC   The specification describes human, murine and rat gankyrin DNA and
CC   polypeptide sequences. Gankyrin polypeptides inhibit tumorigenic
CC   ability and apoptosis induction. The polypeptides and their antibodies
CC   can be used in the diagnosis and treatment of cancers,
CC   e.g. hepatocellular carcinoma, and study of oncogenesis mechanism.
CC   The present sequence represents rat gankyrin.
XX
SQ   Sequence   231 AA;


  Query Match           95.4%;  Score 1110;  DB 20;  Length 231;
  Best Local Similarity  95.1%;  Pred. No. 4.1e-113;
  Matches  214;  Conservative    9;  Mismatches    2;  Indels    0;  Gaps    0;

Qy      1 MEGCVSNLMVCNLAYSGKLEELKESILADKSLATRTDQDSRTALHWACSAGHTEIVEFLL 60
          ||||||||||||||:|||:||||||||||||||||||||||||||||||||||||||||||
Db      1 megcvsnlmvcnlayngkldelkesiladkslatrtdqdsrtalhwacsaghteivefll 60
```